

REMARKS

By this reply, claims 1 and 8 have been amended; claims 16, 25, 36, and 37 have been cancelled; and new claims 38-41 have been added. Accordingly, claims 1-15, 17-24, 26-35, and 38-41 are pending in this application. Of claims 1-15, 17-24, 26-35, and 38-41, claims 17 and 19 were previously withdrawn. No new matter has been introduced by this reply.

In the outstanding Office Action, claims 1-16, 18, 20, 21, 35, and 37 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,211,370 to Powers ("Powers"); and claims 1-7, 15, 16, and 22-37 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,906,577 to Beane et al. ("Beane").

In light of the amendment to independent claim 1, Applicant requests the reconsideration of the rejection of independent claim 1 as being anticipated by Powers. Independent claim 1 has been amended to recite, *inter alia*, "[a] surgical device for use in surgery comprising: a mounting element; a sealing member of pliable material mounted to the mounting element, the sealing member having a normally closed access opening; and at least a portion of the mounting element being movable on insertion of an object to open the access opening while the sealing member maintains substantial sealing engagement with the object." Powers fails to teach or suggest all of these aspects of claim 1.

Powers discloses a variable orifice sealing valve that includes a cylinder 13 held by a first ring 16, 17 and a second ring 18, 19. See Powers, column 2, lines 7 and 12-16. In Powers, a torsion spring tends to force cylinder 13 into a closed configuration,

but the valve is held in a desired position by the meshing of a series of recesses 21 and teeth 21' on the undersurface 22 of outer member 17 with a series of teeth 23 on the upper surface of a collar 24 affixed by pins 25 to outer member 19, such that outer member 17 must be lifted to disengage teeth 23 and recesses 21 to turn the valve. See *Id.* at column 2, lines 17-30. According to Powers, "even when the valve is in a closed configuration, as shown in FIG. 4, an instrument still may be inserted through the center since the elastic cylinder 13 is deformable." *Id.* at column 2, lines 41-44.

On page 2 of the Office Action, it is asserted that an inner member 16 of first ring 16, 17 and an inner member 18 of second ring 18, 19, form the claimed "mounting element," while cylinder 13 forms the claimed "sealing member." Applicant respectfully disagrees. As evidenced by the cited passages above, Powers teaches that cylinder 13 is deformable on insertion of an instrument through cylinder 13. However, Power does not teach or suggest that inner members 16 and 18 of first ring 16, 17 or second ring 18, 19 are movable on insertion of the instrument through cylinder 13. Rather, Power suggests that inner members 16 and 18 are not movable upon insertion of the instrument, since first ring 16, 17 and second ring 18, 19 are fixed by teeth 23 and recesses 21. Since neither of inner members 16 and 18 are movable on insertion of the instrument, Powers fails to teach or suggest, "at least a portion of the mounting element being movable on insertion of an object to open the access opening while the sealing member maintains substantial sealing engagement with the object," as required by amended independent claim 1. A few of the benefits of providing movability on insertion of an object are described on page 24 of Applicant's specification. Reconsideration and withdrawal of the rejection is requested.

Applicant also requests the reconsideration of the rejection of independent claim 1 as being anticipated by Beane. Independent claim 1 now recites, *inter alia*, “[a] surgical device for use in surgery comprising: a mounting element; a sealing member of pliable material mounted to the mounting element, the sealing member having a normally closed access opening; and at least a portion of the mounting element being movable on insertion of an object to open the access opening while the sealing member maintains substantial sealing engagement with the object.” Beane fails to teach or suggest all of these aspects of claim 1.

Beane discloses a wound retractor 200 that has an attached sealing sleeve 204. See Beane, column 9, lines 8, 9, and 18-20. Beane further discloses that “the sealing sleeve can include an iris valve 76 . . . formed from two stiff rings 70 and 72 attached to opposite ends of a tubular piece 74 of elastic material (FIG. 6A). In this configuration, iris valve 76 is open. To seal the opening, or alternatively, to seal around a surgeon’s arm inserted through the opening, the upper ring 72 is rotated relative to the lower ring 70, as a result tubular piece of elastic material 74 becomes twisted and the opening through the tubular piece contracts (FIG. 6B).” *Id.* at column 9, lines 30-39. Thus, Beane does not teach or suggest that tubular piece 74 has a normally closed access opening. Rather, Beane teaches that the opening in tubular piece 74 has an open configuration shown in FIG. 6A when left alone, and that actions, such as rotating upper ring 72 relative to lower ring 70, must be taken in order for the opening in tubular piece 74 to be moved into the closed configuration of FIG. 6B.

Additionally, contrary what is being claimed, Beane teaches that rings 70 and 72 are rotatable after an object (e.g., a surgeon’s arm) is inserted through the opening in

tubular piece 74 to close the opening. See *Id.* at column 9, lines 30-39. Beane does not teach or suggest that rings 70 and 72 are movable on insertion of the arm to open the opening in tubular piece 74. Further, like Powers, Beane also teaches locking the upper and lower rings 70 and 72 using a clasping mechanism 78 and 80, which suggests that movement of upper and lower rings 70 and 72 is restricted. See *Id.* at column 9, lines 39-42.

Since tubular piece 74 does not have a normally closed opening, and rings 70 and 72 are not disclosed as being movable on insertion of the arm to open the opening in tubular piece 74, Beane fails to teach or suggest, “the sealing member having a normally closed access opening; and at least a portion of the mounting element being movable on insertion of an object to open the access opening while the sealing member maintains substantial sealing engagement with the object,” as required by amended independent claim 1. Reconsideration and withdrawal of the rejection is requested.

Claims 2-7, 15, 18, 20-24, 26-35, and 38 depend, either directly or indirectly, from amended independent claim 1, and are therefore allowable for at least the same reasons that amended independent claim 1 is allowable. In addition, the dependent claims recite unique combinations that are neither taught nor suggested by the cited art, and therefore are also separately patentable.

In light of the amendment to claim 8, Applicant requests the reconsideration of the rejection of claim 8 as being anticipated by Powers. Claim 8 has been made into an independent claim, and has been amended to recite, *inter alia*, “[a] surgical device for use in surgery comprising: a mounting element; a twisted sealing member of pliable material mounted to the mounting element, the sealing member having a normally

closed access opening; at least a portion of the sealing member being untwisted on insertion of an object to open the access opening whilst maintaining substantial sealing engagement with the object; and a spring element to bias the sealing member to close the access opening." Powers fails to teach or suggest all of these aspects of claim 8.

Powers discloses that "even when the valve is in a closed configuration, as shown in FIG. 4, an instrument still may be inserted through the center since the elastic cylinder 13 is deformable." Powers, column 2, lines 41-44. However, Powers does not teach or suggest that elastic cylinder 13 is untwisted on insertion of the instrument. Since Powers discloses that elastic cylinder 13 deforms on insertion of the instrument, and does not teach or suggest that elastic cylinder 13 untwists on insertion of the instrument, Powers fails to teach or suggest, "a twisted sealing member of pliable material mounted to the mounting element, the sealing member having a normally closed access opening; at least a portion of the sealing member being untwisted on insertion of an object to open the access opening whilst maintaining substantial sealing engagement with the object; and a spring element to bias the sealing member to close the access opening," as required by independent claim 8. Accordingly, Applicant request reconsideration and withdrawal of the rejection of claim 8.

Beane fails to teach or suggest all of the aspects of independent claim 8 for reasons similar to those discussed with respect to independent claim 1. Thus, Applicant submits that claim 8 is allowable over Beane.

Claims 9-14 depend, either directly or indirectly, from independent claim 8, and are therefore allowable for at least the same reasons that amended independent claim 8 is allowable. In addition, the dependent claims recite unique combinations that are

neither taught nor suggested by the cited art, and therefore are also separately patentable.

New independent claim 39, while being of different scope, is allowable for at least the same reasons that amended independent claim 1 is allowable. New independent claim 39 recites, *inter alia*, “[a] surgical device for use in surgery comprising: a mounting element including a first ring element and a second ring element; a sealing member of pliable material mounted to the mounting element, the sealing member having a normally closed access opening; at least a portion of the sealing member being movable on insertion of an object to open the access opening whilst maintaining substantial sealing engagement with the object; and movement of the sealing member causing movement of one of the first ring element and the second ring element relative to the other of the first ring element and the second ring element.” In Powers, movement of elastic cylinder 13 does not cause movement of inner member 16 or inner member 18 (see the discussion of Powers above in the remarks concerning amended independent claim 1). Thus, Power fails to teach or suggest each of the limitations recited in independent claim 39. Additionally, Beane fails to teach or suggest all of the aspects of independent claim 39 for reasons similar to those discussed with respect to independent claim 1. For all of these reasons, the timely allowance of independent claim 39 is respectfully requested.

Claims 40 and 41 depend, either directly or indirectly, from independent claim 39, and are therefore allowable for at least the same reasons that amended independent claim 39 is allowable. In addition, the dependent claims recite unique combinations that

are neither taught nor suggested by the cited art, and therefore are also separately patentable.

The Office Action contains characterizations of the claims and the related art with which Applicant does not necessarily agree. Unless expressly noted otherwise, Applicant declines to subscribe to any statement or characterization in the Office Action. Further, in discussing the specification, claims, and drawings in this Reply, it is to be understood that Applicant is in no way intending to limit the scope of the claims to an exemplary embodiment described in the specification or abstract and/or shown in the drawings. Rather, Applicant is entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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